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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522 0324 '02 APR 12 A6:36

Implantation or Injectable Dosage Form New Animal Drugs; Sometribove Zinc Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Monsanto Co. which provides for subcutaneous injection of sometribove zinc suspension in healthy lactating dairy cows to increase the production of marketable milk with no restriction on injection site. Three injection sites are recommended.

DATES: This rule is effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0221, e-mail: ssechen@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167, filed a supplement to NADA 140-872 that provides for the use of POSILAC 1 STEP (sometribove zinc suspension) in healthy lactating dairy cows to increase the production of marketable milk. The supplemental NADA provides for subcutaneous injection with no restriction on injection site. Three injection sites are recommended: The neck area, the postscapular region, or the depression on either side of the tailhead. The application is approved as of December 27, 2001, and the regulations are amended in § 522.2112 (21 CFR 522.2112) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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Section 522.2112 is also being amended to provide for changes to the conditions of use approved November 4, 1997. These changes included the use of sometribove zinc suspension beginning during the 9th or 10th week after calving, and the removal of, or changes in, precautionary statements from labeling pertaining to certain reproductive disorders.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.2112 is amended by revising the section heading and paragraph (a), by removing paragraph (c), by redesignating paragraph (d) as paragraph (c), and by revising newly redesignated paragraphs (c)(1) and (c)(3) to read as follows:

§ 522.2112 Sometribove zinc suspension.

(a) Specifications. Each single-dose syringe contains 500 milligrams (mg) sometribove zinc in a prolonged-release suspension.

* * * * *

(c) Conditions of use--(1) Amount. Inject 500 mg every 14 days beginning during the 9th or 10th week (57 to 70 days) after calving and continue until the end of lactation.

* * * * *

(3) Limitations. For use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Administer subcutaneously. To minimize injection site blemishes on carcass at time of slaughter, avoid injections within 2 weeks of expected slaughter. No milk discard or preslaughter withdrawal period is required. Use may result in reduced pregnancy rates and, in first calf heifers, an increase in days open. The incidence of retained placenta may be higher. Treated cows are at an increased risk for clinical mastitis and subclinical mastitis. In some herds, use has been associated with increases in somatic cell counts in milk. Care should be taken to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Use may result in an increase in digestive disorders such as indigestion, bloat, and diarrhea. There may be an increase in the number of cows experiencing periods of "off-feed" (reduced feed intake) during treatment. Cows treated with this product may have increased numbers of enlarged hocks and lesions of the knee (carpal region), and second lactation or older cows may have more disorders

of the foot region. Use has been associated with reductions in hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

Dated: Andrew J. Beaulieu
Andrew J. Beaulieu
Acting Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
March 21, 2002
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